Adopt 17 Cal. Code of Regs. section 100300 to read:

§ 100300. Intellectual Property Requirements for Non-Profit Organizations - Scope.

The regulations of this chapter apply to all CIRM grant awards issued on or after the effective date of these regulations. By accepting a CIRM grant award, the grantee agrees to comply with the provisions of these regulations. Any new or amended regulations adopted by the Independent Citizen's Oversight Committee ("ICOC") will be applied to currently active grants on the start date of the next non-competitive renewal period. Principal investigators, program directors and organizational officials with active CIRM grants will receive notification of revised grant terms and conditions or revised editions of the CIRM Grants Administration Policy as they are released. In addition, all revisions to these regulations will be posted on the CIRM website at www.cirm.ca.gov.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100301 to read:

§ 100301. Intellectual Property Regulations - Definitions.

(a) "Authorized Organizational Official." The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the laws, regulations, requirements, and conditions that apply to grant applications or grant awards.

(b) "Award." The provision of funds by CIRM, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.

(c) "Bayh-Dole Act." Section 6(a) of the federal Patent and Trademark Law Amendments Act as amended (35 U.S.C. §§ 200 212).

(d) "Biomedical Materials." Entities of biomedical relevance produced as a consequence of scientific research including but not limited to unique research resources such as synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. Specific examples include specialized and/or genetically defined cells, including normal and diseased human cells, monoclonal antibodies, hybridoma cell lines, microbial cells and products, viruses and viral products, recombinant nucleic acid molecules, DNA probes, nucleic acid and protein sequences, certain types of animals including transgenic mice and other intellectual property such as computer programs.

(e) "Data." The recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary

analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples).

(f) "For-Profit Organization." An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners.

(g) "Grantee/Grantee Organization." The individual or organization awarded a grant by CIRM that is legally responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activity. The grantee is the entire legal entity even if a particular component is designated in the NGA. All University of California grantee institutions shall be considered as separate and individual grantee institutions.

(h) "Grantee Organization's Share." The revenues received by a grantee organization under a commercial license of a CIRM-funded patented invention remaining after deducting the inventor's share of those revenues.

(i) "Invention." [As used in the Bayh-Dole Act, i.e.,]A discovery that is or may be patentable (novel, useful and non-obvious) or otherwise protectable under Title 35 of the United States Code.

(j) "Invention Disclosure." A description of an invention that triggers a patent bar under U.S. Patent Law.

(k) "Invention Disclosure Form." A written notification to CIRM that a CIRM-funded patentable invention has been made.

(l) "Invention Utilization Report." Applicable to grantee organizations that have previously filed an Invention Disclosure Form, this annual report is a written description of efforts made by authorized organizational officials to commercialize CIRM-funded patentable

inventions. This report will include information about the status of development, date of first commercial sale or use and any licensing fees and/or gross royalties received by the grantee organization relating to CIRM-funded patented inventions.

(m) "Inventor." A person who thinks of, finds, discovers, or creates an invention during the project period of a CIRM grant and using CIRM funds as determined under U.S. Patent Law.

(n) "License Agreement." An agreement by which a patent owner allows another party to make, use and/or sell an invention protected by a patent.

(o) "Licensing Activities." Actions taken by authorized organizational officials, the desired outcome of which is a contractual agreement under which the grantee organization grants permission to another party to use intellectual property under specific conditions.

(p) "Licensing Fee." A one-time cost payable by a licensee to the patent owner typically associated with execution of a license agreement.

(q) "Materials Transfer Agreement." A document ("MTA") which governs the exchange of a substance, element or item (material) to another party for the purposes of research. It limits the commercial exploitation of the material without the permission of the provider party.

(r) "No-Cost License." An agreement to practice an invention protected by a patent where no licensing fee, royalty or any other payment is required of the licensee.

(s) "Non-Profit Organization." A university or other institution of higher education or an organization of the type described in 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501 (c) and exempt from taxation under 501 (a) of the Internal Revenue Code (25 U.S.C. 501 (a)) or any non-profit scientific or educational organization qualified under a state non-profit organization statute.

(t). “Notice of Grant Award.” The document that notifies the grantee and others that an award has been made, contains or references all terms and conditions of the award, and documents the obligation of CIRM funds.

(u) “Office of Technology Transfer.” The office at a grantee institution that is responsible for evaluating, protecting, monitoring and managing an invention portfolio for the public good through overseeing invention disclosures, patent filings, patent prosecution, and negotiating and monitoring licensing agreements.

(v) “Patentable Invention.” A novel, useful and non-obvious invention that advances science and enables new useful applications including therapeutics or diagnostic tools, as determined under relevant patent law.

(w) “Principal Investigator/Program Director.” The principal investigator (“PI”) or program director (“PD”) is an individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and CIRM for the proper conduct of the project or activity. For training programs or similarly structured programs, the PD is the same as the PI.

(x) “Project period.” The total amount of time for which CIRM promises to fund a grant and authorizes a grantee to conduct the approved work of the project described in the application.

(y) “Research Exemption.” The ability to use patented inventions for research purposes free from the threat of patent infringement or costs of licensing fees, royalties or any other payments.

(z) “Research Tool.” A composition or method that broadly facilitates subsequent research.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100302 to read:

§ 100302. Invention Reporting Requirements.

(a) Grantee organizations are required to have written agreements with researchers requiring prompt disclosure of inventions made in the performance of CIRM-funded research.

(b) Within 60 days after an inventor discloses a CIRM-funded invention to a grantee organization, the grantee organization must notify CIRM of the invention through the use of the CIRM Invention Disclosure Form which will be received in confidence by CIRM. The Invention Disclosure Form shall identify the grant under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purpose, operation, and physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify whether a manuscript describing the invention has been submitted for publication. If so, the disclosure shall identify the publication to which the manuscript has been submitted and the submission date.

(c) Grantee organizations must notify CIRM on an annual basis regarding the filing of patent applications that claim inventions made in the performance of CIRM-funded research.

(d) Grantee organization must notify CIRM on an annual basis regarding execution of any licensing agreements of inventions made in the performance of CIRM-funded research.

(e) Grantee organizations must submit annually an Invention Utilization Report that lists all CIRM-funded inventions, patents claiming such inventions and a statement of efforts made to utilize CIRM-funded inventions. Such reports shall include information about the status of development, date of first commercial sale or use and all licensing fees and/or gross royalties received by the grantee organization under licenses of CIRM-funded patented inventions.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100303 to read:

§ 100303. Publication Requirements.

(a) Within 60 days of the publication of CIRM-supported research results in a scientific journal, PIs must submit to CIRM a 500 word abstract written for the general public that highlights the findings of the published body of work. In addition, PIs must submit a biographical sketch to accompany the abstract. The abstract and the biographical sketch will be deposited into the publicly-accessible CELR, to be accessed via the CIRM website.

(b) One copy of each publication resulting from work performed under a CIRM grant must accompany the mandatory annual progress report submitted to CIRM.

(c) In the final manuscript, authors must include the URL of a website where the CIRM MTA (or similar document) can be accessed to facilitate requests for publication-related materials.

(d) CIRM grantees must acknowledge CIRM support of research findings in publications, announcements, presentations, and press releases by the grantees. An example of an acceptable acknowledgement is:

"The research was made possible by a grant from the California Institute for Regenerative Medicine (Grant Number _____). The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of CIRM or any other agency of the State of California."

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100304 to read:

§ 100304. Biomedical Materials.

Grantees shall share biomedical materials described in published scientific articles for research purposes in California within 60 days of receipt of a request and without bias as to the affiliation of the requestor unless legally precluded. Under special circumstances, exceptions to the above are possible with approval by CIRM. Alternatively, authors may provide requestors with information on how to reconstruct or obtain the material. Materials are to be shared without cost or at cost.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100305 to read:

§ 100305. Patent Applications.

(a) Grantee organizations shall bear responsibility for costs associated with patents and patent applications claiming their CIRM-funded inventions.

(b) Grantee organizations shall report on an annual basis filings of such patent applications that claim inventions made in the performance of CIRM-funded research.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100306 to read:

§ 100306. Licensing CIRM-Funded Patented Inventions.

(a) Grantee organizations shall assume responsibility for licensing activities including identification of potential licensees, negotiation of license agreements and documentation of development progress for licenses relating to CIRM-funded patented inventions. Grantee organizations are required to submit a licensing activities report relevant to CIRM-funded patented inventions on an annual basis.

(b) Grantee organizations shall negotiate non-exclusive licenses of CIRM-funded inventions whenever possible. Nevertheless, grantee organizations may negotiate and award exclusive licenses for CIRM-funded inventions if such licenses are necessary to provide economic incentives required to enable commercial development and availability of the inventions. In due diligence relating to such exclusive licenses, grantee organizations shall document development and commercialization capabilities of the intended licensee, and include terms in the license agreement addressing all relevant therapeutic and diagnostic uses for which the invention is applicable.

(c) In exclusive license agreements, grantee organizations shall include terms for commercial development plans to bring the invention to practical application. Such provisions shall include commercial development milestones and benchmarks so that development can be assessed and monitored.

(d) Grantee organizations shall grant exclusive licenses involving CIRM-funded patented inventions relevant to therapies and diagnostics only to organizations with plans to provide access to resultant therapies and diagnostics for uninsured California patients. In addition, such licensees will agree to provide to patients whose therapies and diagnostics will be purchased in

California by public funds the therapies and diagnostics at a cost not to exceed the federal Medicaid price. The CIRM may make access plans available for review by the ICOC on an annual basis.

(e) Grantee organizations shall monitor the performance of exclusive licensees of CIRM-funded patented inventions to ensure that the licensed invention is developed in a timely fashion. Remedies for failure to develop may include modification or termination of a license by the grantee in the event that a licensee is unable to fully develop the rights granted.

(f) Grantee organizations shall negotiate relevant and specific grounds for modification or termination of the license. Examples would include failure to meet agreed-upon commercialization benchmarks, failure to keep the licensed invention reasonably accessible to the public for research purposes, and failure to reasonably meet the agreed-upon plan for access to resultant therapies as described in subdivision (d) of this regulation.

(g) Grantee organizations shall monitor the commercial development activities of the licensees to determine compliance with the terms of the license agreement and include reports of monitoring activities annually to the CIRM.

(h) Grantee organizations shall take administrative action to modify or terminate license rights where necessary and report such action to the SPO.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100307 to read:

§ 100307. Research Exemption.

Grantee organizations agree that California research institutions may use their CIRM-funded patented inventions for research purposes at no cost. Grantee organizations shall ensure that such use is preserved int their licenses of CIRM-funded patented inventions.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100308 to read:

§ 100308. Revenue Sharing.

(a) Grantee organizations shall share a fraction of any net revenues with the inventor(s) in accordance with their established policies. Net revenues are defined as gross revenues minus the inventor's share and direct costs incurred in the generation and protection of the patents from which the revenues are received.

(b) The grantee organization may retain a threshold amount of its share (after payments to inventors) of any revenues received under a license agreement or agreements of any CIRM-funded patented invention(s). Thereafter, the grantee organization shall pay 25% of its share after payments to inventors of such revenues to the State of California for deposit into the State's General Fund unless such action violates any federal law. The threshold amount is $500,000 (in the aggregate) multiplied by a fraction, the denominator of which is the Consumer Price Index, All Urban Consumers, All Items (San Francisco-Oakland-San Jose; 1982-84=100) as prepared by the Bureau of Labor Statistics of the United States Department of Labor and published for the month of February, 2006, and the numerator of which is such Index published for the month in which the grant award is accepted by the grantee.

(c) If funding sources in addition to CIRM were used in the creation of a CIRM-funded patented invention, the return to the State of California of any resultant revenues shall be proportionate to the support provided by CIRM for the discovery of the invention.

(d) Grantees shall apply the grantee organization's share of any revenues earned as a result of CIRM-funded patented inventions to the support of scientific research or education.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

1 Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100309 to read:

§ 100309. Press Release Requirements.

CIRM grantees must notify CIRM prior to any press releases that refer to research findings, collaborations, inventions, patents or licensing activities that arise as a consequence of CIRM funding by contacting the CIRM Communications Officer and the Scientific Program Officer. In the event that the CIRM wishes to participate in a joint press release, the grantee will coordinate with the CIRM Communications Officer.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100310 to read:

§ 100310. March-In Rights.

(a) With regard to CIRM-funded patented inventions, CIRM shall have the right to require the grantee organization, or exclusive licensee of a CIRM-funded invention, to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the grantee organization, or exclusive licensee refuses such request, to grant such a license itself, if the CIRM determines that such an action is required:

(1) Because the grantee organization or the licensee has not made responsible efforts in a reasonable time to achieve practical application of a CIRM-funded patented invention;

(2) Because the licensee has failed to adhere to the agreed-upon plan for access to resultant therapies as described in subdivision (d) of Title 17 Cal. Code Regulations section 100306;

(3) To meet requirements for public use and the requirements have not been satisfied by the grantee organization or its licensee;

(4) To alleviate public health and safety needs which are not reasonably satisfied by the grantee organization or its licensee and which needs constitute a public health emergency.

(b) CIRM will give to the grantee or licensee notice of such determination and the basis on which it was made. CIRM will not exercise its rights described above if the grantee or licensee takes diligent action promptly to cure the deficiency and such deficiency is cured sooner than one year from receipt of notice (or longer period by mutual agreement). With respect to a deficiency described in subdivision (a)(4) of this regulation, CIRM may exercise such right at any time in the event of a public health or safety emergency.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.